

REMARKS

Claims 10, 11, 13-15 and 18-20 are pending in this application.

Information Disclosure Statement

At page 11 of the Action, the Examiner indicates that an initialed copy of the PTO/SB/08 submitted with the IDS filed April 9, 2008 is enclosed. However, the initialed PTO/SB/08 from the IDS filed April 9, 2008 was not enclosed with the Office Action and is not uploaded to PAIR. Applicants' representative contacted the Examiner by telephone to inquire about this matter, and was informed that the IDS has been considered, but a signed copy was inadvertently omitted with the Office Action.

In view thereof, Applicants respectfully request the Examiner to return an initialed copy of the PTO/SB/08 submitted with the IDS filed April 9, 2008, with the next Action.

Applicants further note that at page 3 of the Action, the Examiner states that the references cited in the specification have not been included in the IDS. In response, Applicants note that "the 56th Annual meeting of the Japanese Society of Physical Fitness and Sports Medicine (September 20, 2001)" cited in the specification merely relates to technical background and does not describe plasma protein content nor circulatory plasma volume, which are discussed in the specification. Therefore, this reference has not been included in an IDS. The other references cited in the specification had already been filed as the IDS.

In this regard, it is noted that "the 57th Annual Meeting of the Japanese Society of Physical Fitness and Sports Medicine (September 29, 2002)" was submitted with the IDS filed April 13, 2007, but crossed off by the Examiner on the PTO/SB/08 Form returned with the Office Action mailed August 7, 2007 with a note indicating that a English translation is requested. Applicants subsequently submitted another copy of the English translation of the

Japanese language document with the Amendment filed December 6, 20007 (see page 6 of the "Remarks"), but have not yet received an initialed copy of the PTO/SB/08 Form submitted April 13, 2007 indicating receipt and consideration of the reference and its English translation. Thus, Applicants resubmit a copy of 57th Annual Meeting of the Japanese Society of Physical Fitness and Sports Medicine (September 29, 2002) reference along with an English translation concurrently herewith.

Applicants respectfully request the Examiner to return a copy of the initialed PTO/SB/08 Form with the next Action acknowledging receipt and consideration thereof.

Co-pending Applications

At pages 3-4 of the Action, the Examiner states that if there is any pending U.S. application relevant to the present application, such information should be informed to the Examiner.

In response Applicants note that such information has already been provided. Specifically, co-pending U.S. Patent Application Nos. 10/525,385 and 10/534,734 were cited in the Information Disclosure Statement filed April 13, 2007.

Applicants respectfully request the Examiner to formally acknowledge notification of the co-pending Application in the next Action.

Response to Rejection under 35 U.S.C. §:

At page 6 of the Office Action, claims 10, 11, 13-15 and 18-20 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,458,395 (Emoto), J. Dairy Sci. 83:2819 (Davenport), JP 2001-346528 Abstract and English translation (JP '528) and JP 07-322817 Abstract and English translation (JP '817).

The Examiner essentially maintains her previous position and addresses the previously non-elected invention, according to claim 20, by merely pointing to JP '528 and JP '817, without providing much explanation.

For the reasons of record, Applicants maintain that the Examiner has not made a *prima facie* showing of obviousness in view of the deficiency of the references and with regard to the combination and the reasons therefore.

Specifically, Emoto does not teach the use of a protein that does not coagulate at pH 3 to pH 4, which consists of: (1) whey protein concentrate, whey protein isolate or desalted whey; and (2) gelatin hydrolysates having a number average molecular weight of 500-10,000.

Emoto teaches away from the present invention in the use of a protein that does not coagulate at pH 3 to pH 4, particularly, Emoto states, "It is *necessary* that the protein form an isoelectric gel at the pH of the food products of the invention, i.e., pH 3.3 to 4" (emphasis added). (See column 4, lines 44 to 46.).

Even further, Emoto also fails to disclose gelatin hydrolysates having a number average molecular weight of 500-10,000. Emoto fails to disclose or fairly suggest each and every element of the present invention, and thus, fails to render obvious the present invention.

Further, Davenport fails to remedy the deficiencies of Emoto. Specifically, Davenport fails to teach the use of a protein that does not coagulate at pH 3 to pH 4, which consists of: (1) whey protein concentrate, whey protein isolate or desalted whey; and (2) gelatin hydrolysates having a number average molecular weight of 500-10,000, which are characteristic features of the present invention. To the contrary, Davenport teaches the use of colostrum with whey protein or casein, but not with gelatin hydrolysates having a number average molecular weight of 500-10,000.

Moreover, Emoto and Davenport are not combinable because the proposed modification or combination of the cited references would render Emoto unsatisfactory for its intended purposes and/or change the principle of operations of Emoto. A person of ordinary skill in the art would not consider combining the colostrum product disclosed in Davenport with the gelatinous food product disclosed in Emoto because colostrum is unsuitable for heat treatment, as evidenced in the copy of U.S. Patent No. 6,426,109 B1, submitted with the Amendment filed April 30, 2009. US '109 states, "Colostrum is especially unsuitable for heat treatment, as the high protein content makes it coagulate at elevated temperature"(emphasis added). (See column 1, lines 28 to 30.) On the other hand, the gelatinous food product in Emoto is prepared by mixing and emulsifying the ingredients, and heating the resulting emulsion (see column 6, lines 24 to 59; and Claim 8). The skilled person in the art would not consider incorporating the colostrum product of Davenport with the gelatinous food product of Emoto, which is prepared by heat treatment.

Further still, one of ordinary skill in the art would not have an expectation of success in achieving a suitable product for the purpose of invention. Davenport discloses that the combined use of the colostrum and casein leads to a decline of plasma total protein from the single use of the colostrum (see Table 1 and Fig. 2). It is clear that the plasma total protein is affected by the combination of colostrum with a specific protein. Thus, one of ordinary skill in the art would not have expected a change of plasma total protein with different combinations.

In the Office Action, the Examiner states, "One skilled in the art would know that calcium in natural form, acids, carbohydrates, fat and water all are present in milk which expands plasma volume" (emphasis added). (See page 10, paragraph 2.) However, Davenport states that the hematocrit declined from 0 to 24 h as the plasma volume expanded with colostrum intake (p.

2815, lines 4-6), while dietary treatment had no effect on changes in the hematocrit (p. 2815, lines 27-28). Thus, contrary to the Examiner's opinion, based on the disclosure of Davenport, one of ordinary skill in the art would believe that plasma volume expansion is affected by the specific component in colostrum, rather than by common components in the diet, such as calcium, acids, carbohydrates, fats or water.

Also, the present invention is patentable for the additional reason that the instant invention achieves unexpected results that are nowhere disclosed, taught or suggested by the cited references. As previously pointed out, in the present invention, administering a gel composition containing (1) and (2) above significantly increases plasma volume, plasma total protein content and plasma albumin content. The effect of the invention is specifically disclosed in the Example of the specification. Such effects would not be expected by the cited references, whether taken alone or in combination, because the references are silent as to a gel composition containing (1) and (2) above, much less the effects of a gel composition containing a combination of (1) and (2) above as in the present invention.

In view of the above, the present invention is patentable over Emoto and Davenport, taken alone or in combination. The newly cited references, JP '528 and JP '817, fail to remedy the deficiencies of Emoto and Davenport. The Examiner has failed to address any of the points discussed above.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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